REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed November 9, 2009. Claims 1, 3-6, 21-28, and 31-42 were pending and rejected in view of cited art. Claims 1, 3-6, 21-28, and 31-42 are now pending in view of the above amendments.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

B. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claims 1, 3-6, 21-28, and 31-32 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Publication No. 2002/0082679 (*Sirhan*) in view of U.S. Patent No. 6,254,631 (*Thompson*) further in view of U.S. Patent No. 6,174,329 (*Callol*). Applicant respectfully traverses because a *prima facie* case of obviousness has not been established. Applicant respectfully asserts that the claimed invention is a "stent system for placement in a body lumen."

In accordance with Applicant's understanding, *Sirhan* teaches a source (25) of a therapeutic agent (28) can be "disposed or formed adjacent [to] at least a portion of either or both surfaces of the expandable structure, within the interior of the structure disposed between the two surfaces, or any combination thereof," (paragraph 0025) which is shown in Figures 1A-1C and Figures 2A-2N. Also, the source 25 can be within the expandable structure when a matrix (40) is formed by the expandable structure (16) and the therapeutic agent 28 (paragraphs 0116-0117).

The source can also be configured as a rate controlling material or have a rate controlling member deposited on the source. As such, various configurations of stents that include a source of a therapeutic agent are disclosed. However, what is not disclosed by *Sirhan* is a stent that is ready "for placement in a body lumen" that has a "polymer-free coating consisting of a therapeutic agent disposed directly on the exterior or interior surface of the stent." Additionally, *Sirhan* teaches that the surface of the expandable structure can be pre-processed by abrasion. However, the only example of *Sirhan* that shows pre-processing by abrasion is Example 2 which also shows that a surface of a metal stent is roughed, coated with a drug, and then a parylene rate controlling barrier is applied over a drug-coated and roughened surface. Accordingly, the roughening of the surface of an expandable stent structure is only taught as an intermediate article before receiving a drug coating and then a rate controlling material coating. *Sirhan* does not teach or suggest an expandable stent structure that has a roughened surface with a "polymer-free external coating consisting of a therapeutic agent disposed directly on the exterior or interior surface of the stent." Thus, *Sirhan* does not teach a stent with a "polymer-free external coating consisting of a therapeutic agent" as the outermost external surface that is ready "for placement in a body lumen."

In accordance with Applicant's understanding, *Thompson* teaches a stent that has a smooth tissue facing surface and a luminal surface that is at least partially roughened. The reason that *Thompson* has a luminal surface that is roughened is to facilitate deployment with a balloon. The roughened luminal surface is taught to provide better grip with a slippery balloon surface, and no other reason is provided for the roughed luminal surface. *Thompson* also teaches that the side surfaces can be roughened, but the tissue facing surface remains smooth. In fact, *Thompson* specifically teaches that the tissue facing surface must remain smooth, and provides teachings for manufacturing processes that will result in the tissue facing surface to remain smooth (column 3, line 42 through column 4, line 20). *Thompson* is completely devoid of teaching or suggesting stents that have therapeutic agents or polymeric or polymer-free coatings, and does not teach "a polymer-free external coating consisting of a therapeutic agent."

In accordance with Applicant's understanding, *Callol* teaches against rough stent external surfaces because such surface irregularities can act as loci for unwanted platelet adhesion (column 4, lines 25-32). To prevent such external surface irregularities, *Callol* teaches an external protective layer (20, 34, and 40) to provide a smooth surface that protects against scratches and flaking (Figures 3, 6, and 7; column 5, lines 5-12). The only instance that *Callol*

teaches sandblasting the stent is to roughen the surface of the stent substrate to facilitate adhesion with the protective layer (column 7, lines 19-27). *Callol* is completely devoid of teaching or suggesting stents that have therapeutic agents, and does not teach "a polymer-free external coating consisting of a therapeutic agent."

Applicant respectfully asserts that the combination of *Sirhan, Thompson,* and *Callol* does not teach or suggest each and every element of the currently pending claims. The combination does not teach a stent system that is ready "for placement in a body lumen" that has a "roughened exterior surface, a roughened interior surface, and side surfaces, wherein at least a portion of the exterior surface and the interior surface is roughened to a predetermined extent for coating; and a polymer-free external coating consisting of a therapeutic agent disposed directly on the exterior or interior surface of the stent," as recited in claim 1. Only the *Sirhan* reference teaches a therapeutic agent, so the combination must include the therapeutic agent as taught by *Sirhan*, and thereby the combination cannot result in a "polymer-free external coating consisting of a therapeutic agent disposed directly on the exterior or interior surface of the stent" because *Sirhan* does not teach such an external coating consisting of a therapeutic agent for a stent that is ready "for placement in a body lumen." The combination of *Sirhan, Thompson*, and *Callol* results in a stent that has a smooth tissue facing surface (taught by *Thompson* and *Callol*) where the smooth tissue facing surface can be a coating, such as a rate controlling material (taught by *Sirhan*) or protective coating (taught by *Callol*), or the smooth tissue facing surface can be the stent substrate (taught by *Thompson*). Additionally, the combination of references results in: (1) a stent that has no coating (taught by *Thompson*) with the drug within the expandable structure; or (2) has a drug that is applied to a stent substrate and coated with a rate controlling material or the drug is contained within the rate controlling material matrix. Thus, the combination of references does not teach or suggest a stent with a roughened exterior surface and/or a stent with a "polymer-free coating consisting of a therapeutic agent disposed directly on the exterior or interior surface of the stent," and thereby a *prima facie* case of obviousness has not been established with regard to clam 1.

Applicant respectfully asserts that there is no valid reason to combine these references without first reading the Applicant's application and using it as a roadmap to reconstruct the claimed invention with impermissible hindsight analysis. First, *Sirhan* teaches stents that have therapeutic agents (1) within the expandable stent structure; (2) coated on a roughened surface and then covered with a rate controlling external surface layer; or (3) mixed with a rate

controlling material and coated on the expandable stent structure. Second, *Thompson* teaches a stent with a roughened luminal surface and a smooth tissue facing surface, and does not even teach or suggest coatings or therapeutic agents. Third, *Callol* teaches a protective coating over the stent so that protects against scratches and flaking. Neither *Thompson* nor *Callol* teach drug eluting stents. There is not a common nexus between these references that is sufficient for making the combination. Accordingly, there is no valid reason for combining a reference that teaches drug eluting stents (*Sirhan*) with a reference that teaches stents with a smooth tissue facing surface and a rough luminal facing surface (*Thompson*) and with a reference that teaches a stent having a protective coating (*Callol*). The only way these references can be combined is by first reading the Applicant's application and then picking and choosing selected portions of *Sirhan, Thompson,* and *Callol* without considering each reference in its entirety. Such a combination is through the use of improper hindsight.

Applicant also respectfully asserts that the combination of references teaches away from the presently claimed invention. The teaching in *Thompson* that requires the tissue facing surface to be smooth cannot be selectively abandoned and the combination of references must result in a stent that has a smooth tissue facing surface. On the other hand, the tissue facing surface of the stent system of claim 1 is the exterior surface, and claim 1 recites that the exterior surface is roughened. Thus, the combination of references teaches away from the invention of claim 1.

Applicant respectfully asserts that a *prima facie* case of obviousness has not been established because the combination of references does not teach each and every element of the presently pending claim 1, there is no motivation to combine the references, and the combination of references actually teaches away from the invention recited in claim 1. Thus, Applicant respectfully requests withdrawal of the rejection and allowance of the currently pending claims.

II. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejects claims 33-42 under 35 U.S.C. § 103(a) as being unpatentable over *Sirhan* in view of *Thompson*, and *Callol*, as applied supra, further in view of U.S. Patent No. 6,387,123 (*Jacobs*). Applicant respectfully traverses because a *prima facie* case of obviousness has not been established.

The above discussion of the combination of *Sirhan, Thompson*, and *Callol* is relevant to this remark and incorporated herein by specific reference. Claim 33 is allowable because *Jacobs*

does not cure the deficiencies of the combination of *Sirhan, Thompson,* and *Callol* described above with regard to claim 1, and claim 33 depends from claim 1.

In accordance with Applicant's understanding, *Jacobs* teaches annealing a multilayered or coated stent to prevent problems with galvanic corrosion, and that the annealing can form "positive bonds between the disparate materials, annealing also has the desirable effect of creating a grain structure within the applied metal coatings, especially within the outer skin, which then serves to enhance the overall strength of the stent." As such, *Jacobs* teaches annealing the coated stent so that the external coating has improved overall strength. *Jacobs* does not teach coating the annealed stent with a coating consisting of a therapeutic agent or any other additional coating having a therapeutic agent.

Applicant respectfully asserts that there is no valid reason to combine these references without first reading the Applicant's application and using it as a roadmap to reconstruct the claimed invention with impermissible hindsight analysis. In addition to the reasons that there is no valid reason to combine *Sirhan, Thompson,* and *Callol*, there is also no valid reason to further combine *Jacobs* therewith. Also, *Jacobs* teaches a stent with a radiopaque layer that is then coated with stainless steel encapsulating skin that is annealed so that positive bonds are formed between the different substrate, layers, and coatings materials. There is not a common nexus between these references that is sufficient for making the combination. Additionally, there is no logical connection between the references that teach abrasion or sandblasting (e.g., *Sirhan, Thompson,* and *Callol*) with a reference that teaches annealing multiple layered or coated stents for improved strength. Just because these references exist does not allow them to be combined without a valid reason. The only way these references can be combined is by first reading the Applicant's application and then picking and choosing selected portions of *Sirhan, Thompson, Callol*, and *Jacobs* without considering each reference in its entirety. Such a combination is through the use of improper hindsight.

Applicant also respectfully asserts that the combination of references teaches away from the presently claimed invention. The teaching in *Jacobs* that requires multiple layers or coatings of different types of materials to be annealed teaches away from the present invention for at least two reasons: (1) *Jacobs* teaches multilayered stents where the outer surface is a metal encapsulating skin that is annealed; (2) the annealing is referred to as the "final step" in the manufacturing process, which would degrade any therapeutic agent deposited on the stent. The coating of the presently claimed invention includes a therapeutic agent, and annealing thereof

would degrade the therapeutic agent. Thus, the combination of references teaches away for the invention of claim 34 or 39.

Applicant respectfully asserts that a *prima facie* case of obviousness has not been established because there is no motivation to combine the references, and the combination of references actually teaches away from the invention recited in claims 34 or 39. Claims 35-38 and 40-42 depend from claims 34 or 39 and are thereby allowable for the same reasons. Claim 33 is allowable because Jacobs does not cure the deficiencies of the combination of *Sirhan, Thompson* and *Callol* with regard to claim 1 from which claim 33 depends. Thus, Applicant respectfully requests withdrawal of the rejection and allowance of the currently pending claims.

C. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 9th day of February, 2010.

Respectfully submitted,

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